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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,044	07/10/2003	Dan M. Berger	AM100056 D1	4109

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EXAMINER	
SACKEY, EBENEZER O	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,044	BERGER ET AL.	
	Examiner	Art Unit	
	EBENEZER SACKEY	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *2-9,11-18,21 and 23-33* is/are withdrawn from consideration.

5)☒ Claim(s) *10,19 and 34* is/are allowed.

6)☒ Claim(s) *22* is/are rejected.

7)☒ Claim(s) *20 and 35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/10/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-10 are pending.

Information Disclosure Statement

The Information Disclosure Statement filed 02/ is acknowledged and has been entered into the file. Signed copies of the 1449 are attached herewith.

Response to Restriction

Applicant's election with traverse of Group IV in the reply filed on 07/06/04 is acknowledged. The traversal is on the ground(s) that the restriction is unwarranted because there is ample justification to keep all the pending claims and subject matter in a single application. This is not deemed persuasive because each Group is directed to compounds, which are different from each other and are capable of supporting their own patents. The wide disparity among the groups requires that many divergent fields be searched, including all of the indicated classes and subclasses of U.S.Patent system (i.e., 546 and 548) as well as the non-patent literature. Applicants have requested modification of the restriction groups to those compounds classified in 546 (Groups I and III-IX) and their methods of use (Group XI, claims 22-33). This request cannot be honored because the various diseases in claims 22-33 are unrelated and would be expected to raise differing issues of patentability.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific neoplasm's (colon cancer, lung cancer, colonic polyps), does not reasonably provide enablement for all neoplasm's. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1) Nature of invention.

2) State of prior art.

3) Level of ordinary skill in the art.

4) Level of predictability in the art.

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

The claim is drawn to a method of treating, inhibiting the growth of, or eradicating neoplasm. According to Stedman's Medical Dictionary, neoplasm is an abnormal tissue that grows by cellular proliferation more rapidly than normal and continues to grow after the stimuli that initiated the growth cease. Neoplasm's can be *benign tumor* or *malignant* (cancer).

Applicants' critical failure is lack of a single specific neoplasm they intent to treat and the complete lack of data showing efficacy of their compounds against that neoplasm. Tumors vary from those so benign that they are never treated; to those so virulent that present therapy is useless. The present specification says, in effect: here are the compounds and how to make them. You figure out what neoplasm's they might be useful against. This is not the "immediate benefit to the public" required by *Cross et al., v. Iizuka et al.,* 224 USPQ 739, and *Nelson v. Bowler* 206 USPQ 881.

2) State of the prior art.

The state of the art in neoplasm therapy is the remarkable advances in chemotherapy, which have seen the development of specific compounds to treat "specific" types of neoplasm. The great diversity of diseases falling within the "tumor" or "malignant" category means that it is contrary to medical understanding that any agent (let alone a genus of thousands of compounds) could be generally effective against such diseases.

Evidence involving a single compound and two types of cancer was not found sufficient to establish the enablement of claims directed to a method of treating seven types of cancer with members of a class of several compounds. See *In re Buting, 163 USPQ 689.* To make clearer the lack of enablement for treatment of all neoplasms extrinsic evidence is supplied by Draetta (Ann. Reports Med. Chem.) Dreatta et al., "Annual Reports in Medicinal Chemistry", Vol. 31, pages 241-246, 1996, Academic Press, San Diego. The final sentence on page 246 "[a]lthough many still think about the need for a magic bullet as a cure for all cancers, our knowledge of the molecular mechanism underlying this disease make the prospect of developing such a universal cure very unlikely". Since no universal cure for neoplasm has been developed, it follows that there is no correlation between the assays relied upon by applicants and the ability to treat all neoplasm's. Thus, those assays are not sufficient to enable such a claim.

3) Level of ordinary skill in the art.

It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The intractability of neoplasms generally is clear evidence that the skill level in this art is low relative to the difficulty of the task.

4) Level of predictability in the art.

Determining if any particular neoplasm would be treatable with applicants' compounds would require clinical trials in each disease with each compound.

Considering the hundreds of compounds covered by claim 10, and the multitude of different neoplasms, this is a very large degree of experimentation.

5) Amount of direction and guidance provided by the inventor

The direction concerning neoplasm treatment is found on pages 124-133.

Applicants' *in vitro* assay described on pages 134-135. Applicants have not disclosed formulations, doses or dosing schedules required to practice their invention.

6) Existence of working examples.

There is no working example of neoplasm treatment in man or animals in the specification.

7) Breadth of claims.

The breadth of claim includes all of the thousand of compounds of formula (I) as well as the presently unknown list of diseases embraced by claim 22. Thus, the scope of the claim is broad.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation as disclosed in the specification on pages 1-5 because of the existence of the innumerable amounts of diseases embraced by the claim. The skilled artisan would have numerous amounts of modifications to perform in order to arrive at the instantly claimed method.

MPEP 2164.01(a) state, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright,* 999 F.2d 1557, 1562, 27, USPQ 2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to practice applicants' invention.

Claim 35 is objected to as referring back to the specification for support, which is improper since claims must be independent of the specification and not refer back to it for support or completeness. Applicants should note that claims, may contain chemical and mathematical formulas, but shall not contain drawing or flow diagrams as claimed herein. See 37 CFR § 1.58.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (703) 305-6889. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is

(703) 308-1235.

EOS
September 28, 2004

Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1600
Technology Center 1